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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JESSICA PENELOW and CHRISTINE BRANCACCIO, Plaintiffs, v. JANSSEN PRODUCTS, LP, Defendant.	Case No. 12-7758 (ZNQ)(JBD) **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MOTION AND MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR JUDGMENT AS A MATTER OF LAW

TABLE OF CONTENTS

TABLE OF AUTHORITIES

STATUTES

RULES

REGULATIONS

INTRODUCTION

This is a simple case masquerading as something complex. To show an FCA violation, a relator must prove each of four elements: causation, materiality, falsity and scienter. Because the elements are conjunctive, failure of one is failure of all. Here, Relators fall woefully short on at least three—causation, materiality and falsity—each of which provides a separate and independent basis for the grant of judgment as a matter of law in favor of Janssen.

First, Relators introduced no evidence on which a reasonable jury could find that Janssen caused the submission of false claims because they failed to identify a single doctor whose judgment was overcome by Janssen's alleged off-label marketing—much less that the alleged conduct was integral to the submission of claims or that claims would not have been submitted without the alleged off-label marketing. Relators presented no testimony whatsoever from any treating physician that Janssen's alleged conduct caused him or her to prescribe Prezista or Intelence for any allegedly off-label use.

Second, Relators introduced no evidence on which a reasonable jury could find that Janssen's alleged off-label marketing was material to the government's payment decisions. To the contrary, the evidence shows that the government has actual knowledge of Relators' allegations and continues to pay for Prezista and Intelence to this day. Evidence that the government generally cares about off-label

marketing is plainly insufficient to show that alleged off-label marketing had a natural tendency to influence the submission of a claim.

Third, Relators introduced no evidence on which a reasonable jury could find that the at-issue claims were false because they failed to identify a single false claim, let alone introduce evidence that any claims were submitted for uses other than medically accepted indications.

Frankly, no evidence is no evidence is no evidence. However the light shifts in the kaleidoscope, it shines the same from every angle. The evidence Relators put forth is illusory and cannot salvage their desperate attempt to fit the proverbial square peg into a round hole. Unlike other FCA cases addressing drug marketing, this one sought to impose liability on Janssen for promoting HIV drugs for their indicated purposes—a theory that is nearly without precedent (and as far as Janssen is aware, the first of its kind to result in a verdict against a defendant). There is no evidence that ***could*** support a verdict on this theory because the law does not recognize it. At trial, relators sought to escape this reality by blurring the line between misbranding and FCA liability. But because Relators' failed to put forward evidence supporting these three essential elements of their claim, the Court should enter judgment as a matter of law.

Judgment as a matter of law is also warranted for the following additional reasons:

- Relators failed to prove their state-law claims. The Court shared its concerns right before closing that Relators had failed to put on any evidence in support of their state-law claims, and those concerns were well-founded. It is indisputable that state payors have their own coverage rules, and it is equally indisputable that there is ***no evidence*** of those coverage rules in the record. The only testimony on this score is from Relators' own witnesses' admissions that the coverage requirements vary from state to state. As courts have repeatedly held, these claims must therefore fail as a matter of law.
- The jury's verdict on the number of claims and amount of damages cannot be sustained for several reasons: (a) the damages amount was based on the wrong measure of damages under Third Circuit law; (b) Relators' damages model was based on a series of assumptions that were contradicted by the undisputed evidence; (c) the jury's estimation of the number of claims and amount of damages was arbitrary and unsupported by the evidence; and (d) there is no basis to identify the number of federal as opposed to state claims or damages.
- The jury's verdict must also be set aside because Relators' claims are barred under the government-action and public-disclosure bars of the FCA and by the Constitution.

BACKGROUND

Relators filed the instant action on behalf of the federal government, twenty-six states and the District of Columbia, alleging fifty-six counts under the federal False Claims Act ("FCA"), the federal Anti-Kickback Statute ("AKS"), and the false claims acts of various states. (*See* Second Am. Compl. at 1-2, Dkt. 90.) The claims arise from Janssen's purported kickback scheme and off-label promotions of two HIV/AIDS drugs: Prezista and Intelence. (*Id.*)

Relators' first theory of FCA violations is premised on Janssen's allegedly improper promotion of its HIV medications in four ways: (1) describing Prezista's impact on lipids in ways that the relators allege was misleading (the "lipid-based claims"); (2) promoting Prezista for treatment-naïve patients before it was FDA-approved for that patient population in October 2008; (3) promoting Intelence for once-daily dosing, when it was FDA-approved for twice-daily dosing; and (4) promoting Intelence for treatment-naïve patients, when it was never FDA-approved for that patient population. Collectively, these are referred to as Relators' "Promotional Claims."

According to Relators' damages expert, Israel Shaked, the Promotional Claims resulted in the submission of 481,265 false claims to federal and state governments, culminating in $361.9 million in damages. (*See* 6/3/24 Tr. 5493:14-25.) Shaked did not detail any payor-by-payor breakdown among these alleged

false claims or damages. The jury rejected Relators' theory in part, awarding $120,004,736 under the federal FCA and $30,001,184 under state FCAs based on 159,574 purportedly false claims. (Verdict Form at 2, 4-5, Dkt. 435.) The claims finding did not distinguish between claims submitted to federal and state healthcare programs because, pursuant to Relators' request and over Janssen's objection, the verdict form was crafted simply to ask for a total claims number that Relators asserted would cover "ADAP, Medicaid, Medicare." (6/11/24 Tr. 7949:5-7952:3.) Nor did the verdict form disaggregate damages by each of the four challenged promotional claims. (Verdict Form at 2, 4-5, Dkt. 435.)

Relators' second theory is premised on Janssen's alleged violation of the Anti-Kickback Statute ("AKS") through its payments to doctors who served as speakers to educate other doctors about Prezista and Intelence. The jury completely rejected Relators' AKS claims. (Verdict Form at 3, 6-7.)

STANDARD

Under Rule 50(b) of the Federal Rules of Civil Procedure, a post-verdict judgment as a matter of law is proper when there is no "legally sufficient evidentiary basis for a reasonable jury to find for [the non-moving party]." *See Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App'x 246, 251 (3d Cir. 2008) (citation omitted). A Rule 50(b) motion requires that "the court . . . review all the evidence in the record." *Reynolds v. Univ. of Pa.*, 747 F. Supp. 2d 522, 534 (E.D. Pa. 2010)

(citing *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150 (2000)), *aff'd*, 483 F. App'x 726 (3d Cir. 2012). "[T]he court must draw all reasonable inferences in favor of the nonmoving party[]" and "give credence to the evidence favoring the nonmovant," but it must also credit "that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses.'" *Reeves*, 530 U.S. at 150-51 (citation omitted).[1]

The key question in evaluating the sufficiency of the evidence "is not whether there is literally *no evidence* supporting [the non-movant], but whether there is evidence upon which a reasonable jury could properly have found its verdict." *Johnson v. Campbell*, 332 F.3d 199, 204 (3d Cir. 2003) (emphasis omitted) (quoting *Gomez v. Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995)). The rule is not "that a scintilla of evidence is enough" to defeat a motion for judgment as a matter of law. *Gomez*, 71 F.3d at 1083. Instead, "there must be a conflict of *substantial evidence* to create a jury question." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1184 (3d Cir. 1993) (citation omitted).

[1] In accord with this Court's instructions, Janssen presented its oral Rule 50(a) motion before the Court to preserve its rights under Rule 50(b) instead of filing a written submission. (*See* 6/3/24 Tr. 5389:4-5393:1 (agreeing on procedure for Rule 50(a) motions); 6/6/24 Tr. 6979:4-6980:11 (same); *id.* 7430:14-7460:9 (detailing specific basis for Janssen's Rule 50 motion); *id.* 7727:10-7728:15 (renewing after close of Janssen's case); *id.* 7761:4-21 (after rebuttal case).)

"'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984) (citation omitted).

Conclusory testimony that is unsupported by the rest of the record is not sufficient to support a verdict. *See Walter v. Holiday Inns, Inc.*, 985 F.2d 1232, 1240-43 (3d Cir. 1993). And "a jury is not authorized to base a decision on conjecture or speculation." *Rosario v. City of Union City Police Dep't*, 263 F. Supp. 2d 874, 878 (D.N.J. 2003), *aff'd*, 131 F. App'x 785 (3d Cir. 2005) (granting defendant's Rule 50(b) motion to vacate jury's cumulative award of $3 million in damages).

Here, Relators failed to present sufficient evidence to prove their claims, and the Court should grant judgment notwithstanding the verdict.

ARGUMENT

I. RELATORS FAILED TO PROVE THEIR FCA CLAIMS.

To prevail on the Promotional Claims, Relators needed to prove (among other things): (1) causation, (2) materiality, and (3) falsity. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). For the reasons below, the evidence fails to support the portion of the jury's verdict in favor of

Relators on any of these elements, and Janssen is therefore entitled to judgment notwithstanding the verdict.

A. Relators Failed To Prove Causation.

First, Relators failed to prove that Janssen was the but-for or proximate cause of the submission of any false claim by a Part D plan sponsor to CMS.

Relators had to prove that Janssen's alleged conduct was a "substantial factor" in causing the submission of false claims to Medicare. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-45 (3d Cir. 2004). Relators thus had the burden of proving both that (1) Janssen was the but-for cause of the submission of false claims—i.e., that the claims would not have been submitted in the absence of Janssen's alleged conduct, and (2) Janssen's alleged conduct was the proximate cause of the submission of those claims, i.e., that its conduct was "integral" to their submission. *See Petratos*, 855 F.3d at 491. They proved neither.

1. Relators Failed To Prove But-For Causation.

Relators failed to produce substantial evidence that Janssen's alleged conduct was the but-for cause of the submission of any false claim for reimbursement by any Part D plan sponsor.

First, there was a total failure of proof on the point of claim submission—i.e., that anything Janssen did was the but-for cause of a Part D plan sponsor's submission of allegedly false claims to CMS for reimbursement.

Under Part D, it is the ***plan sponsor*** that must determine whether a prescription is covered by Medicare.[2] Thus, Relators needed to prove not merely that Janssen persuaded doctors to prescribe off-label, but that Janssen engaged in conduct that somehow subverted Part D plan sponsors' processes for identifying and weeding out prescriptions that are not eligible for reimbursement under Medicare. *Cf. Petratos*, 855 F.3d at 492 (explaining that in indirect-causation cases, the proper focus "should not be whether the alleged fraud deceived the prescribing physicians, but rather whether it affected CMS's payment decision").

The United States itself has taken this position as to a relator's causation burden, arguing in another FCA case that the government "does not support th[e] theory of liability" that off-label marketing alone causes "subsequent claims for

[2] *See* CMS, Final Rule, *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005) ("Pt. D Final Rule"); 42 C.F.R. § 423.566(a) (assigning coverage determinations to Part D plan sponsors); CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2010) ("Manual") ("Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for 'medically-accepted indications.'"). Although the Manual was not admitted into evidence at trial, the Court "may take judicial notice of public records." *See Liberty Int'l Underwriters Can. v. Scottsdale Ins. Co.*, 955 F. Supp. 2d 317, 325 (D.N.J. 2013) (citation omitted). This includes CMS manuals. *See Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 259 (E.D. Pa. 2020) (finding that CMS manuals were "both self-authenticating and subject to judicial notice"). Moreover, the Third Circuit and the Government itself view Medicare benefit manuals as relevant authority for construing Medicare statutory and regulatory requirements. *See Petratos*, 855 F.3d at 488 (relying on Medicare Benefit Policy Manual to construe Part A requirements and noting that the Government's brief relied on the same authority).

reimbursement" to be false. Br. for United States as Amicus Curiae at 12 n.4, *United States ex rel. Solis v. Millennium Pharms., Inc.*, Nos. 15-16953 et al. (9th Cir. filed Nov. 17, 2016) ("*Solis* Br.") (attached as Ex. 1). Rather, the relator must show that the statements caused submissions for reimbursement because of "false or misleading statements ***material to reimbursability***." *Id.* at 11-12 (emphasis added). That means, for example, making "false or misleading statements that a particular drug use is covered under the public health insurance programs," or that "an unapproved drug use is supported by a compendium citation." *Id.* at 12. This argument makes sense. Even if an off-label representation were to cause a ***prescription*** to be written, it would be impossible to conclude that such a representation specifically caused the eventual submission of that prescription by a Part D plan sponsor to Medicare for reimbursement absent a misrepresentation about ***Medicare coverage*** of that prescription, especially where off-label use of a drug occurs in the absence of promotion.

The opinion of the U.S. Court of Appeals for the Second Circuit in *United States ex rel. Polansky v. Pfizer*, 822 F.3d 613 (2d Cir. 2016), illustrates the point. It involved the alleged off-label promotion of Lipitor, a cholesterol-lowering drug, for use in patients without elevated cholesterol. As the court explained, the FDA permits doctors to make their own prescribing decisions, meaning that off-label

prescriptions will be presented to CMS with or without any alleged promotion for such uses, making any causal role of promotion "unclear":

> Accordingly, it is unclear just whom Pfizer could have caused to submit a "false or fraudulent" claim: The physician is permitted to issue off-label prescriptions; the patient follows the physician's advice, and likely does not know whether the use is off-label; and the script does not inform the pharmacy at which the prescription will be filled whether the use is on-label or off.

Id. at 619-20. Indeed, because Part D plan sponsors understood that Lipitor was prescribed both for on-label and off-label purposes, a given sponsor "could hardly be understood to have operated on the assumption that the physician writing the prescription was certifying implicitly that he was prescribing Lipitor" on-label. *Id.* at 620 (citation omitted); *accord United States ex rel. Keeler v. Eisai, Inc.*, 568 F. App'x 783, 794 n.18 (11th Cir. 2014) (per curiam) (citing *Polansky* approvingly on similar record).

The same is true here. Relators' own witnesses acknowledged that doctors prescribing Prezista and Intelence were in no way restricted from considering off-label data and studies or from using their medical judgment to write off-label prescriptions. (*See* 5/13/24 Tr. 1128:3-1129:13 (Wilhelm); *see also* 5/21/24 Tr. 2518:5-2519:7 (Dr. Glatt testifying that some of the ways doctors exercise good medical judgment is by reading medical literature and attending conferences); *id.* 2521:12-2522:4 (Dr. Glatt acknowledging that off-label prescribing can be medically appropriate and is, indeed, prevalent in the HIV context).) And on cross-

examination, Shaked admitted that his model identified approximately ***200,000*** prescriptions for the uses at issue covered by Medicare Part D that were written by about 3,600 doctors who had no contact with Janssen at all. (*See* 6/3/24 Tr. 5504:7-5505:1). Given the pervasiveness of alleged off-label prescribing for HIV patients, the only reasonable inference (just as in *Polansky*) is that Part D plan sponsors would have been aware that a significant portion of Prezista and Intelence prescriptions would have been for off-label uses.[3] Thus, just as in *Polansky*, it is "unclear" at best how alleged off-label promotion by Janssen could be the but-for cause of the submission of claims for reimbursement. And by the same logic, it also defies reason to conclude from these facts that any Part D plan sponsor was impliedly certifying that any Prezista or Intelence prescription was for on-label use when submitting such claims to CMS for reimbursement. There was zero evidence at trial to this effect.

Second, Relators' proof of causation also failed at the first link in their causal chain: that any allegedly improper promotion actually influenced any doctor's prescribing decision. As the Third Circuit recognized in *Petratos*, prescribing is driven by patient-specific considerations. 855 F.3d at 487-88.

[3] CMS also understood at the time Part D was enacted that off-label prescribing "may be the mainstay of medical practice for successfully managing certain conditions, such as . . . HIV/AIDS." Pt. D Final Rule, 70 Fed. Reg. at 4260.

Accordingly, as other courts have held in analogous circumstances, individualized proof is needed to establish the effects of marketing on prescribing decisions. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 454 (E.D.N.Y. 2009) (because of the doctor- and patient-specific nature of prescribing decisions, "[i]ndividualized proof is needed . . . to overcome the possibility that a . . . patient was prescribed Zyprexa for some reason other than" the alleged marketing).

Relators' own witnesses uniformly acknowledged this common-sense fact in the context of HIV specifically, conceding that the decision regarding which combination of medications to prescribe for an HIV patient is a complex and fact-dependent one, turning on many considerations other than promotional messaging. (*E.g.*, 5/15/24 Tr. 1878:14-1879:15 (Brancaccio conceding doctors take many factors into account when prescribing medications); 5/21/24 Tr. 2514:3-2515:1 (Dr. Glatt testimony about the many factors doctors consider when selecting a medication).) Relators presented ***no*** doctor- or patient-specific evidence to demonstrate the alleged off-label marketing effect on prescribing in any individual doctor's office. Nor did they present testimony from any treating physician that Janssen's alleged off-label promotion caused her to prescribe Prezista or Intelence. To the contrary, Relators' medical expert, Dr. Glatt, conceded that:

- an individual doctor's medical judgment about HIV care should supersede any generalized guidance on the topic (*see* 5/21/24 Tr. 2513:6-22);

- a doctor's individualized judgment could properly lead her to make a medically appropriate decision to prescribe medications off-label (*id.* 2521:8-16);

- it is critical for doctors to thoroughly reassess new patients referred by other doctors and existing patients at every single visit (*id.* 2520:2-16); and

- there are circumstances where even he would consider it medically appropriate to prescribe Prezista and Intelence in the precise manner at issue here (*see infra* at p. 36).

Taken together, the only thing Relators proved is what Janssen argued all along: in the HIV context, the cause of a doctor's decision to prescribe medications, including off-label, is a highly individualized assessment subject to the independent, medical judgment of a treating physician. There was no evidence that a doctor's judgment was hijacked by Janssen's promotional messages in even a single instance, much less across hundreds of thousands of prescriptions.[4]

[4] Relators' attempt to substitute aggregate proof for the individualized proof that is actually required is unavailing as a matter of law. Federal courts have repeatedly rejected generalized proof of causation in analogous cases under RICO, which, like the FCA, incorporates common-law causation principles. *See, e.g.*, *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051-52 (N.D. Cal. 2009) (rejecting generalized causation allegations and, instead, requiring "specific information" available and relied upon, as well as whether a prescription would not have been written if not for the allegedly off-label promoted use), *aff'd*, 464 F. App'x 651 (9th Cir. 2011). Relators have previously relied on *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013), but to prove causation there, plaintiffs relied on an expert who used regression analysis to show a causal connection between the fraudulent marketing and the quantity of off-label prescriptions written. *Id.* at 29-30. Relators made no such showing here. Although Shaked performed a statistical analysis, he did not even claim to show causation between Janssen's conduct and prescribers' behavior, testifying only about an

(cont'd)

Thus, because Relators have failed to present any evidence about any individual prescription at issue here, they have failed to establish the causation element of their FCA claim.

2. Relators Failed To Prove Proximate Causation.

Even if Relators could establish but-for cause, there is still a failure of proof on the causation element because they did not establish proximate cause.

As the Third Circuit put it in *Petratos*, a relator must also prove that the conduct at issue is "integral" the submission of false claims. 855 F.3d at 491. This proximate-causation requirement is based on common-law principles. *E.g.*, *United States v. Luce*, 873 F.3d 999, 1012 (7th Cir. 2012) ("The statutory language of the FCA does not suggest that Congress sought to depart from the established common-law understanding of causation in fraud cases."). As other federal courts have held in construing common-law proximate-causation standards in the analogous context of third-party payor claims about allegedly fraudulent off-label marketing of prescription drugs under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), proximate causation may be lacking where the causal chain is "***too*** indirect or contingent." *Sidney Hillman Health Ctr. of*

observed "strong relationship" between the two and rejecting the contentions that doctors wrote prescriptions "because" or "as a result" of messages from sales representatives. (*See* 6/3/24 Tr. 5546:12-22.)

Rochester v. Abbott Lab'ys, 873 F.3d 574, 578 (7th Cir. 2017) (emphasis added) (citing *Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010)).[5]

In *Sidney Hillman*, for example, two welfare-benefit plans sued the manufacturer of Depakote, alleging that the manufacture had improperly marketed it for off-label purposes, causing physicians to prescribe the drug, patients to fill the prescription, and (ultimately) third-party payors like the plaintiffs to pay for them. *Id.* at 575. The U.S. Court of Appeals for the Seventh Circuit concluded that this "causal chain [wa]s too long to satisfy" proximate causation. *Id.* at 578. As it explained, "some off-label uses of Depakote may be beneficial to patients"; some physicians may have been "apt to write such prescriptions whether or not Abbott promoted off-label uses"; and some physicians "may not have changed their prescribing practices at all" or in response to information from sources other than Abbott. *Id.* at 577. Because there were "so many layers, and so many independent

[5] *Sidney Hillman* applied proximate causation in the RICO context, but the Supreme Court has made clear that proximate causation applies in RICO cases in accord with common-law principles. *See Holmes v. Secs. Inv. Prot. Corp.*, 503 U.S. 258, 269 (1992). Janssen is not contending that only the most direct misrepresentations are actionable under the FCA. But proximate causation principles bar claims of injury that, as here, are "several levels removed in the causal sequence." *Sidney Hillman*, 873 F.3d at 578.

decisions, between promotion and payment," proximate causation could not be met. *Id.* at 578.[6]

The same reasoning applies here. Relators' theory of causation relies on precisely the type of downstream injury that that is "too remote from its causal agent . . . to satisfy" the proximate cause requirement. *Steamfitters Loc. Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 921 (3d Cir. 1999). For this reason, too, Relators failed to prove causation as a matter of law.

B. Relators Failed To Prove Materiality.

Relators also failed to prove materiality. The federal government has had full knowledge of Relators' allegations for over a decade, yet CMS is still paying for Prezista and Intelence, and no government agency—federal or state—has taken any other measure to prevent alleged off-label promotion or prescribing of these

[6] Although the Third Circuit has not ruled directly on the question in an analogous case, it cited this line of cases with approval in *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 804 F.3d 633, 642-43 (3d Cir. 2015), but found causation was plausibly alleged on distinguishable facts—because false statements were made directly by the defendant to the payors. *Sidney Hillman* recognized this distinction. 873 F.3d at 578 (explaining that *Avandia* "agree[d] with the Second Circuit's position as a rule," but held that alleging proximate causation was possible "***when misrepresentations are made directly to Payors***, leading them to add certain drugs to their formularies, which means that they pay more per prescription than they would otherwise.") (emphasis added). Here, there was no evidence of direct misrepresentations made by Janssen to CMS, nor any evidence that CMS paid any more for Janssen's HIV drugs than it would have were alternative HIV drugs prescribed.

drugs. As a result, the evidence cannot support the conclusion that the conduct alleged was material to CMS's payment decision.

Materiality is a "demanding" and "rigorous" requirement. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192, 194 (2016). And it is not met where "the Government would have paid the claims with full knowledge of the alleged noncompliance." *Petratos*, 855 F.3d at 490. That is true regardless of whether, as a technical matter, the claim at issue fails to meet a statutory "condition of payment," or where some "'minor or insubstantial' noncompliance" might have been shown. *Id.* at 489-90 (quoting *Escobar*, 579 U.S. at 194).

Here, the evidence shows that the government had actual knowledge of Relators' allegations, including evidence offered in support of those allegations. (*See* 5/7/24 Tr. 240:15-20 (Graham testifying that she "went to the DOJ" with her claims); 5/8/24 Tr. 357:11-358:19, 360:5-361:21; 5/15/24 Tr. 1845:12-1846:17 (Brancaccio testimony that she shared information regarding the present lawsuit with the government); 5/23/24 Tr. 3491:24-3493:23, 3497:23-3500:18 (Penelow testimony regarding interview with and overview of allegations provided to the government); DX-8518 (email attaching memo to send to government summarizing Relators' claims) (attached as Ex. 2); DX-8856 (email noting the government had asked for evidence at a prior meeting) (attached as Ex. 3); DX-

2372, at 22 (Brancaccio's admission that all evidence was provided to government) (attached as Ex. 4); DX-8511, at 21 (same as to Penelow) (attached as Ex. 5).)

The evidence also shows that the government continues to pay for Prezista and Intelence to this day. (*See* 5/28/24 Tr. 3916:3-18 (Evans testifying that she has not seen any evidence that CMS has ever stopped reimbursing for Prezista or Intelence since 2006).) This record is conclusive. As the Third Circuit held in *Petratos*, materiality is lacking where the record shows that the "[g]overnment would have paid the claims with full knowledge of the alleged noncompliance." 855 F.3d at 490. That is the case here.

The government's continued payment—and its determination that any deviation from its coverage requirements was immaterial—makes sense in light of its liberal policy ensuring coverage of HIV medications. In its 2010 National HIV/AIDS Strategy for the United States, the White House declared its vision to create "unfettered access" to life-extending care. (DX-3005, at 3 (attached as Ex. 6).) CMS recognizes antiretroviral drugs as one of six protected classes of drugs, and Part D sponsor formularies must include these drugs. (*See, e.g.*, DX-8851 (email from Eric Sherr attaching and explaining Interim Final Rule on Protected Classes in Medicare Part D) (attached as Ex. 7); 5/9/24 Tr. 826:16-19 (Strand agreeing that protected status shows CMS "has made a decision that it wants people to have easy access to these HIV medicines").

Relators' attempted proof of materiality consisted entirely of evidence to the effect that "the government"—not necessarily CMS specifically—***generally*** cares about off-label marketing. For example, they elicited speculative (and inaccurate) testimony from Sara Strand that the government generally does not pay for off-label prescriptions. (*See* 5/9/24 Tr. 904:15-905:12.) Similarly, Relators pointed to other settlements with the government (including the two corporate integrity agreements, or "CIAs") as evidence that the government cares in general about off-label promotion.

None of these arguments have merit. ***First***, Relators' evidence of other government actions and settlements establishes, at most, that the government "would be entitled to refuse payment were it aware of the violation," which the Supreme Court expressly rejected as insufficient to establish materiality in *Escobar*, 579 U.S. at 195. This argument also fails to grapple with the fact that the allegations in this case concern the use of HIV medications ***to treat HIV***. As such, it bears no resemblance to the other examples that Relators have cited of government enforcement in response to off-label promotion, which generally involve promotion of drugs for unapproved indications.

That distinction is significant because the alleged "off-label" uses at issue in this case concern minor alleged departures from labeling—not uses for wholly different diagnoses or conditions, which may implicate institutional concerns about

paying for inefficacious treatment. Here, there was no proof that even a single "off-label" Prezista or Intelence prescription did not work. The distinction from typical off-label cases is also significant because, in the context of HIV, CMS would necessarily have paid for some other, equally expensive medication had it not covered Prezista or Intelence. Indeed, it was undisputed at trial that Prezista was priced at parity with the market leader, meaning the government paid no more for Prezista than it would have for an alternative drug. (*See* 5/22/24 Tr. 3008:2-25.) Nor did the government pay any more for prescriptions of Intelence once-daily than twice-daily, which affected only dosing interval of the same drug quantity. Accordingly, Relators failed to demonstrate that any of the alleged false claims did, or could have, affected the government's decision to pay, as required for materiality.

Second, Relators' reliance on the CIAs is especially misplaced because the existence of the CIAs—combined with the government's inaction on Prezista and Intelence—independently ***forecloses*** proof of materiality. As the U.S. Court of Appeals for the Sixth Circuit held in *United States ex rel. Maur v. Hage-Korban*, 981 F.3d 516 (6th Cir. 2020), where a CIA is in place as a result of a prior FCA suit alleging similar prior conduct, and review by a related oversight organization is ongoing at the time of the relator's allegations in a subsequent suit, "it can be

assumed that the government would be aware if the same fraudulent scheme continued or was restarted." *Id.* at 528 (cleaned up) (citation omitted).

Like the CIA in *Maur*, the CIAs here expressly provided for retention of an Independent Review Organization ("IRO"). (*See* RX-423, § III.D.1.a, at 16 & app'xs A & B (attached as Ex. 8); RX-361, § III.E.1.a, at 26 & app'xs A-C (attached as Ex. 9).) And the CIAs also specifically charged the IROs with responsibility for overseeing the general category of alleged activity at issue in this case—i.e., "the dissemination of materials relating to off-label uses of products." (*See* RX-423 app'x B at 2-3; *see also* RX-361 app'x B at 2, 4; 5/28/24 Tr. 3868:3-7 (Evans affirming that the "very products and the very programs" at issue here were part of the 2010 CIA).) Given the insight the IROs had into the types of alleged marketing practices at issue in this case, "it can be assumed that the government would be aware if the same [alleged] fraudulent scheme continued or was restarted" with respect to Prezista and Intelence. *Maur*, 981 F.3d at 528 (cleaned up) (citation omitted). Yet the government took no action with respect to these drugs—and it never stopped reimbursing prescriptions of them—further precluding any finding of materiality. (*See* 5/28/24 Tr. 3916:3-7 (Evans agreeing that she has "not seen any evidence that [the government] halted reimbursement for" Prezista or Intelence); *id.* 3904:2-14, 3917:6-18 (Evans conceding that Janssen

was not subject to any stipulated penalties or exclusion from reimbursement programs due to noncompliance with the 2010 and 2013 CIAs).)

For these reasons, too, Relators' claims fail as a matter of law.

C. Relators Failed To Prove Falsity.

Relators also failed to prove that any claim was false.

In a case alleging that a pharmaceutical company caused "false claims" for medications it manufactured to be "submitted to the Medicare program," the relator must prove that the company caused the submission of claims for reimbursement that failed to meet Medicare's "conditions for payment." *Petratos*, 855 F.3d at 486-87. For Medicare Part D, a prescription of a Part D drug is covered as long as it is for a "medically accepted indication" and, where Part D plan sponsors require it, the prescription is "reasonable and necessary." 42 U.S.C. §§ 1395w-102(e)(1) & (e)(3)(A), 1395y(a).

The relator must also "provide 'evidence of the actual submission of a false claim,'" meaning not merely alleged evidence of a "scheme" pursuant to which "illegal payments must have been submitted," but the false claim itself. *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 98 (3d Cir. 2018) (citations omitted).

Relators proved none of these things. As elaborated below, Medicare does not bar coverage of the uses of Prezista and Intelence alleged in this case, and Relators in any event failed to identify any specific false claim.

1. Relators Failed To Prove That The Alleged Uses Of Prezista And Intelence Were Not "Medically Accepted Indications."

First, Relators failed to proffer evidence that any claim at issue was not for a medically accepted indication.

"Medically accepted indication" means "any use for a covered outpatient drug which is approved" under the FDCA or supported by certain compendia. 42 U.S.C. §§ 1395w-102(e)(4), 1396r-8(k)(6).[7] As CMS elaborates in its *Medicare Prescription Drug Benefit Manual*, "[m]edically-accepted indication refers to the ***diagnosis or condition*** for which a drug is being prescribed, ***not the dose*** being prescribed for such indication."[8] And ***Part D plan sponsors*** "determine whether the statutory definition of 'medically accepted indication' is met with regard to the particular use of a drug."[9]

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[7] Janssen preserves its argument that Part D imposes no such requirement. *See Layzer v. Leavitt*, 770 F. Supp. 2d 579, 587 (S.D.N.Y. 2011) (holding that Part D "does not impose a ['medically accepted indication' requirement]").

[8] Manual ch. 6, § 10.6 (emphases added).

[9] Pt. D Final Rule, 70 Fed. Reg. at 4261; 42 C.F.R. § 423.566(a) (assigning coverage determinations to Part D plan sponsors); Manual ch. 6, § 10.6 ("Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for 'medically-accepted indications' . . . .").

On this question—Part D plan sponsors' determination of whether the alleged off-label uses of Prezista and Intelence in this case were for medically accepted indications—there was a total failure of proof. As Janssen reiterated throughout the trial, Relators failed to proffer even one witness or piece of evidence on the decisions of Part D plan sponsors.

In the absence of evidence of final determinations on the coverage questions from Part D plan sponsors themselves, Relators at least needed to elicit competent expert testimony on this topic. *Cf. United States v. White*, 492 F.3d 380, 403 (6th Cir. 2007) ("The Medicare program operates within a complex and intricate regulatory scheme and we cannot say that the average lay person, including any Medicare beneficiary, commands a working knowledge of Medicare reimbursement procedures."). As Relators themselves argued in successfully opposing the submission of CMS documents to the jury, "interpretat[ions] of rules and regulations and CMS guidelines" would need to be provided, if at all, by "expert witnesses." (6/11/24 Tr. 8044:22-8045:3.)[10] But Relators failed to call such an expert. Because Relators failed to proffer any competent evidence of how Part

[10] Relators' position has shifted and contradicted itself on this issue. Relators previously contended that any requirements of CMS should be included in jury instructions. (Dkt. 409, at 2.) But they also successfully opposed any instruction on Part D's requirements. (Dkt. 424-1, at 27 (opposing instruction); *see generally* Dkt. 424-11 (final instructions omitting Part D charge).)

D plan sponsors would interpret "medically accepted indication" as relevant here, Janssen is entitled to judgment as a matter of law on the issue of falsity.

Even ignoring this issue, Relators' arguments that the four uses at issue were not medically accepted indications, fail for two reasons: (1) the use of Prezista in patients with elevated lipids was not barred by the label; and (2) the other uses, constituted "medically accepted indications" under the Part D framework.

(a) Use Of Prezista With Lipid Conditions Is A Medically Accepted Indication.

Relators' principal assertion is that use of Prezista in patients with lipid conditions was not a medically accepted indication because the drug's labeling contains lipid risk information in the Adverse Reactions section of the label. This argument fundamentally misapprehends the law and is unsupported.

As noted above, "[m]edically-accepted indication refers to the ***diagnosis or condition*** for which a drug is being prescribed."[11] There was no dispute that Prezista was being used for an indicated condition (HIV). And the inclusion of lipid side effects in the Adverse Reactions section of the label does not narrow Prezista's indication. "There is a distinction between off-label marketing to achieve a treatment not contemplated by the label . . . and marketing to a patient population not specifically mandated by the label." *United States ex rel. Polansky v. Pfizer,*

[11] Manual ch. 6, § 10.6 (emphases added).

Inc., 914 F. Supp. 2d 259, 266 (E.D.N.Y. 2012), *aff'd*, 822 F.3d 613. Similarly, it is not the case that every "advisory snippet" in an FDA-approved label may be converted into a "prohibitory mandate" to support an FCA claim. *Id.* at 260. Where the label provides data but "the doctor's clinical judgment is . . . the determinative factor" as to how those data are to be used, then the data "serves as a recommendation, not a limitation or prohibition." *Id.* at 264-65.

In *Polansky*, for example, the relator argued that because the "Indications and Usage" section of the Lipitor label incorporated NCEP Guidelines recommending use of statins in patients with certain risk factors, "any marketing of the drug for patients outside the Guidelines' range is 'off-label marketing,' resulting in the filing of false claims under the False Claims Act." *Id.* at 262. The District Court rejected this "drastically elongated reach of the False Claims Act." *Id.* Because it was undisputed that Lipitor was approved to treat cholesterol, and the guidelines were not "prohibitory," the question of how to prescribe Lipitor was left to the doctor's judgment. *Id.* at 264. Thus, the court refused to "relieve government insurers of the obligation to pay for drugs that doctors believe certain of their patients need, and that the patients themselves want, in order to improve their health." *Id.* at 260.

The same logic applies here. Just like the NCEP Guidelines in the case of Lipitor, the data in the Adverse Reactions section are not "prohibitory." Instead,

again like the NCEP Guidelines, Adverse Reactions data are included when "useful to health care practitioners making treatment decisions and monitoring and advising patients."[12] Relators' own witnesses conceded this character of the lipid information in this section of the label. Dr. Glatt admitted that "[p]rescribing Prezista for someone with a lipid condition ***is not off the FDA label***" and that whether to prescribe Prezista for such a patient is a matter of medical judgment. (*See* 5/21/24 Tr. 2514:3-2515:1, 2526:6-8, 2537:16-2538:7, 2540:13-16 (emphasis added).) Brancaccio similarly acknowledged that a patient's lipids are simply a factor that HIV-doctors consider, monitor and manage when prescribing Prezista and other medications. (*See* 5/15/24 Tr. 1861:25-1864:2.)

In short, the lipid data in the Adverse Reactions section are "advisory snippet[s]," making "the doctor's clinical judgment . . . the determinative factor" as to how those data are to be used. *Polansky*, 914 F. Supp. 2d at 260, 264. They do not restrict the "medically accepted indication" for Prezista and therefore do not establish falsity under the FCA.

[12] FDA, *Guidance for Industry: Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* at 2 (Jan. 2006), https://www.fda.gov/media/72139/download (attached as Ex. 10).

(b) The Three Other Uses Of Prezista And Intelence Are Also Medically Accepted Indications.

Relators also failed to prove that use of Prezista or Intelence in treatment-naïve patients or use of Intelence once daily are not medically accepted indications.

First, prescriptions to treatment-naïve patients are for a medically accepted indication. As explained above, CMS defines "medically accepted indication" in terms of the "diagnosis or condition" for which the drug is being prescribed.[13] Here, there is no dispute that the Prezista and Intelence prescriptions at issue were prescribed to treat HIV, the "diagnosis or condition" for which both are indicated.

That the labels identify use in a particular population does not change the analysis, as *Polansky* again illustrates. In that case, the label in relevant part stated that "[l]ipid-altering agents" like Lipitor "should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate," referring to NCEP Guidelines reproduced in Table 6 of the label as follows:[14]

[13] Manual ch. 6, § 10.6.

[14] *See* 9/21/2005 Lipitor Label at 12, https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020702s042lbl.pdf (attached as Ex. 11); *see also Polansky*, 914 F. Supp. 2d at 261 (reproducing same table).

TABLE 6. NCEP Treatment Guidelines: LDL-C Goals and Cutpoints for Therapeutic Lifestyle Changes and Drug Therapy in Different Risk Categories

Risk Category	LDL-C Goal (mg/dL)	LDL Level at Which to Initiate Therapeutic Lifestyle Changes (mg/dL)	LDL Level at Which to Consider Drug Therapy (mg/dL)
CHD [a] or CHD risk equivalents (10-year risk >20%)	<100	≥100	≥130 (100-129: drug optional) [b]
2+ Risk Factors (10-year risk ≤20%)	<130	≥130	10-year risk 10%-20%: ≥130 10-year risk <10%: ≥ 160
0-1 Risk factor [c]	<160	≥160	≥190 (160-189: LDL-lowering drug optional)

[a] CHD, coronary heart disease

[b] Some authorities recommend use of LDL-lowering drugs in this category if an LDL-C level of < 100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL-C, e.g., nicotinic acid or fibrate. Clinical judgement also may call for deferring drug therapy in this subcategory.

[c] Almost all people with 0-1 risk factor have 10-year risk <10%; thus, 10-year risk assessment in people with 0-1 risk factor is not necessary.

Citing this language, the relator argued that Pfizer was "restricted . . . from marketing the drug to doctors to be used on patients whose risk profiles fell outside the parameters indicated by the NCEP Guidelines." *Polansky*, 914 F. Supp. 2d at 262. The District Court rejected this argument, holding that the specification of one population in the Indications and Usage section did not give rise to FCA liability for prescriptions written to patients outside that population—even though "it [wa]s unclear whether Lipitor works for two specific classes of patients with certain types of high cholesterol." *Id.* at 264.

The same rationale applies here. Relators' argument is that use of Prezista and Intelence in treatment-naïve populations was not a medically accepted indication because the "Indications and Usage" sections of the label specify

treatment-experienced populations. But as in *Polansky*, the labels here contain no "prohibitory" language with respect to other populations. *Id.* At most, the relevant labels state that safety and efficacy "have not been established" in treatment-naïve populations.[15] But that is no different from *Polansky*, in which it was similarly "unclear whether Lipitor works for two specific classes of patients with certain types of high cholesterol." *Id.*

Second, prescriptions for Intelence once daily also satisfy the medically accepted indication requirement. CMS ***expressly excludes*** dosing considerations from the definition of "medically accepted indication," which again "refers to the ***diagnosis or condition*** for which a drug is being prescribed, ***not the dose*** being prescribed for such indication."[16] Reflecting this policy, CMS data do not even contain dosing instructions, as Relators' data expert Ian Dew admitted at trial (5/31/24 Tr. 5285:22-5286:15), meaning ***no representation is ever even made to CMS regarding whether a drug is taken once or twice daily***—precluding the possibility of any ***false*** representation on this issue.

Finally, all of Relators' contrary arguments are misplaced because they conflate what CMS deems to be a "medically accepted indication" with what the FDA would deem to be "on-label." CMS "recognize[s] the value of off label

[15] DX-1007A, at 14 (attached as Ex. 12); DX-1045A, at 2 (attached as Ex. 13).

[16] Manual ch. 6, § 10.6 (emphases added).

prescribing" and has clarified that nothing in Part D "preclude[s] . . . prescribers from prescribing drugs for off label indications, provided the drug is prescribed for a 'medically accepted indication.'"[17] CMS also specifically understands that "off-label use is critically important and may be the mainstay of medical practice for successfully managing certain conditions, such as . . . HIV/AIDS."[18] And CMS has stated that Part D plans are expected to accommodate national guidelines and offer complete treatment options for HIV.[19]

Relators' constricted definition of "medically accepted indication" would frustrate CMS policy by forcing Medicare beneficiaries whose doctors determine

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[17] Pt. D Final Rule, 70 Fed. Reg. at 4261 (citation omitted).

[18] *Id.* at 4260. Relators' rigid construction of "medically accepted indication" would lead to an absurd result: that CMS (part of HHS) would refuse to cover off-label uses of HIV drugs that another part of HHS expressly endorsed in treatment guidelines.

[19] *Id.* at 4260 ("We are looking to existing national standards to inform our review at the drug level, and Part D plans will be expected to accommodate national guidelines and offer complete treatment options for a variety of medical conditions, including . . . HIV."). To this end, during at least some of the timeframe at issue, the HHS guidelines—one of the most important of the many factors doctors consider when prescribing HIV medications (*see* 5/20/24 Tr. 2316:12-21 (Glatt explaining the importance of guidelines))—referenced properly prescribing Prezista and Intelence in the precise manner at issue here. (*See, e.g.*, RX-1356, at 46 (including a study suggesting Intelence "once-daily" may be a potential option for treatment-naïve patients) (attached as Ex. 14); RX-1354, at 43-44 (listing Prezista boosted with ritonvair as one of two "preferred PI" medications in part because of its favorable lipid profile) (attached as Ex. 15); RX-1352, at 24 (excerpting Janssen's clinical trial data results that supported using Prezista for treatment-naïve patient population) (attached as Ex. 16).)

they need off-label HIV treatments to pay for those treatments out of pocket. In the absence of express restrictions on coverage of the prescriptions at issue in this case, the Court should reject such a perverse policy outcome. As the *Polansky* court put it, CMS would want to "avoid the negative reaction that the public would likely have if a patient's doctor decided that the patient should use a statin to lower his cholesterol, but then had to tell the patient that the patient was going to have to pay for the drug himself because public insurers refused to cover it." 914 F. Supp. 2d at 266. Such a policy calculus applies, if anything, with even greater force in the context of HIV, especially in light of CMS's express recognition of the importance of covering the full range of possible treatments for that diagnosis.

Accordingly, Relators failed to prove any prescription should not have been covered on the ground that it was not for a medically accepted indication.

2. Relators Failed To Prove Any Prescription Of Prezista Or Intelence Was Not "Reasonable And Necessary."

Relators also failed to prove that any prescription should not have been covered on the ground that it was not reasonable or necessary, both because they failed to prove that this requirement applied at all, and because they failed to prove that any prescription failed to meet it even if it did apply.

First, Relators failed to prove that the "reasonable and necessary" requirement applied to any prescription. The Medicare statute provides that ***Part D plan sponsors*** "***may*** exclude" from coverage "any covered Part D drug . . . for

which payment would not be made ***if*** section 1395y(a) . . . applied" to Part D. 42 U.S.C. § 1395w-102(e)(3)(A) (emphases added).[20] Section 1395y(a) is the source of the "reasonable and necessary" criterion that is mandatory in Medicare Parts A and B, but left to the discretion of plan sponsors to apply under Part D.[21] As the U.S. government has put it, the language in § 1395w-102(e)(3)(A) means that "Part D prescription drug plans ***may elect*** to deny coverage" for prescriptions that are not reasonable and necessary. *Solis* Br. at 5 n.2 (emphasis added). Here, Relators did not proffer any evidence that any Part D plan sponsor "elect[ed]" to apply this requirement. For that reason alone, Relators failed to prove that any "reasonable and necessary" requirement applied to any prescription at issue.

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[20] *See also* Pt. D Final Rule, 70 Fed. Reg. at 4230 (explaining that "a Part D plan may exclude from coverage covered Part D drugs for which payment may not be made under section 1862(a) of the Act if applied to Part D," i.e., "items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, except those vaccines identified in section 1862(a)(1)(B) of the Act as covered Part B vaccines"); Manual ch. 6, § 20.4 ("[A] Part D sponsor may exclude from qualified prescription drug coverage any Part D drug . . . [f]or which payment would not be made if items and services are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . .").

[21] The meaning of the permissive "***may***" in § 1395w-102(e)(3)(A) is indisputable: exclusion of coverage on the basis that a prescription is not "reasonable and necessary" is ***optional***—and entirely within the discretion of the Part D plan sponsor, meaning Medicare will cover such prescriptions if the sponsor decides not to exclude them. *E.g.*, *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171-72 (2016) (The "word 'may' . . . implies discretion.").

Second, and in any event, Relators failed to prove that any prescription failed to meet the "reasonable and necessary" requirement. The relevant inquiry focuses on the "*individual* patient," and it turns on "accepted standards of medical practice and the medical circumstances of the *individual case*." *Petratos*, 855 F.3d at 488 (quoting Medicare Benefit Policy Manual, ch. 15, § 50.4.3).[22] Thus, Relators needed to prove as to each claim for which they seek to recover that the Prezista or Intelence prescription at issue was not reasonable or necessary as a matter of "accepted standards of medical practice and the medical circumstances of the *individual case*." *Id.* at 488 (citation omitted).

Relators have not proven this, nor could they have. The undisputed evidence at trial from multiple witnesses—including several independent physicians who testified as fact witnesses—is that there were valid reasons for prescribing Prezista and Intelence for each of the four uses alleged by Relators in this case, and that such prescriptions would turn on the needs of the patient and the independent medical judgment of the physician. (*See, e.g.*, 5/31/24 Tr. 5211:11-20 (Dr. Hsu agreeing that he wrote prescriptions for Prezista and Intelence based on his "best medical judgment"); 6/6/24 Tr. 6756:23-25 (similar testimony by Dr. Frank); *id.* 6812:8-21 (similar testimony by Dr. McMeeking); 6/10/24 Tr. 7692:2-6 (similar

[22] *Petratos* expressly construes "reasonable and necessary" in the context of Medicare Parts A and B, where that requirement applies. *See* 855 F.3d at 488.

testimony by Dr. Mills); 6/7/24 Tr. 6912:9-6918:4 (Dr. Rosenberg describing the myriad factors that go into prescribing decisions for HIV patients).)

Even Dr. Glatt conceded that there are circumstances where it would be medically appropriate for a doctor to prescribe Prezista and Intelence precisely for the allegedly off-label uses at issue here. For example, Dr. Glatt acknowledged that, under certain circumstances, it would be medically appropriate for a doctor to prescribe Prezista to a treatment-naïve patient even before the 2008 label change. Dr. Glatt similarly admitted there are certain circumstances where it would be medically appropriate to prescribe Prezista to someone with a known lipid condition. With respect to Intelence, Dr. Glatt admitted that a K103N mutation would justify the off-label use of the medication in treatment-naïve patients. And even though Dr. Glatt testified that ***he*** does not think once-daily Intelence would be appropriate, he nevertheless conceded that other doctors and studies suggested appropriate circumstances could exist for precisely such a prescription. (5/21/24 Tr. 2320:15-24, 2524:12-17, 2537:16-2538:7, 2540:13-16, 2545:10-2546:12.)[23]

[23] At most, Relators have proven that Dr. Glatt might have disagreed with certain prescriptions in particular cases (though without actually identifying even one example of such a case). But "a clinical judgment . . . cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1281 (11th Cir. 2019).

Because Relators did not show that it was unreasonable and unnecessary for any "individual doctor" to prescribe Prezista or Intelence to any "individual patient" based on the particular "medical circumstances of the individual case," *Petratos*, 855 F.3d at 488-89 (emphases omitted) (citation omitted), they failed to prove falsity.

3. Relators In Any Event Failed To Identify Any Individual Claim.

To prove a claim under the FCA, a relator must provide "evidence of the actual submission of a false claim." *Greenfield*, 880 F.3d at 98 (citation omitted). Relators cannot "merely describe a private scheme in detail but then allege that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Id.* (cleaned up). Thus, "aggregate information reflecting the amount of money expended by Medicaid on off-label prescriptions [is] insufficient on its own to support a False Claims Act claim because it [does] not show an actual false claim made to the Government." *Id.* at 99 (cleaned up). That means Relators here had the burden of "provid[ing] evidence of at least one false claim" submitted for payment to CMS to satisfy their burden of proof. *Id.* They have not done so. For this reason, too, Janssen is entitled to judgment as a matter of law.

II. RELATORS FAILED TO PROVE THEIR STATE-LAW CLAIMS.

Janssen is entitled to judgment notwithstanding the verdict on Relators' claims premised on submissions of claims for reimbursement to state Medicaid or AIDS Drug Assistance Programs ("ADAPs").[24] Indeed, the Court has already expressed its "concerns about how the state law claims were presented during this trial." (6/11/24 Tr. 7906:7-12.) Those concerns are well-founded for at least two reasons: (1) Relators failed to establish the coverage requirements of any of these programs; and (2) Relators in any event failed to prove the elements of any of their claims as to these programs.

A. Relators Failed To Establish That Any Medicaid Or ADAP Program Would Deny Coverage Of The Prescriptions At Issue.

As with their federal claim, the premise of Relators' state-law claims is that the prescriptions of Prezista and Intelence at issue were not eligible for reimbursement, which implicates the "conditions for payment" established by the respective states' Medicaid and ADAP programs. *Petratos*, 855 F.3d at 486-87. But Relators failed even to ***identify*** the requirements of these programs, much less ***prove*** them, and for that reason alone, their state-law claims fail as a matter of law.

[24] That includes every claim that Relators brought under state corollaries to the FCA—statutes enacted by California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington and the District of Columbia. (Second Am. Compl. at 1, Dkt. 90.)

State Medicaid programs have their own coverage requirements; they are not bound to copy Medicare. The federal Medicaid statute provides that states "***may*** exclude or otherwise restrict coverage" of a drug because "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i) (emphasis added). As noted above (*see supra* at 34 & n.21), "may" is a discretionary term, and in a prior case the U.S. government expressly recognized that this language is permissive in nature, *see Solis* Br. at 5 n.2 (noting that Medicaid "***permits*** states to limit coverage" on this basis) (emphasis added). As the federal Medicaid office put it with respect to HIV drugs specifically in December 1994, "it is within the discretion of each individual State to establish certain limitations on the provision of drugs under the boundaries of the drug rebate program."[25]

ADAP likewise imposes no restriction on off-label uses of HIV drugs; it requires only that states receiving ADAP grants "ensure that the therapeutics included on the list" of drugs established by HHS "are, ***at a minimum***, the treatments provided by the State." 42 U.S.C. § 300ff-26(c)(1) (emphasis added).

[25] Letter from Sally K. Richardson to State Medicaid Director[s] at 1, Dec. 5, 1994, https://www.medicaid.gov/federal-policy-guidance/downloads/smd120594.pdf (attached as Ex. 17). The letter is admissible evidence as a public record under Fed. R. Evid. 803(8). And the Court may take judicial notice of it under Fed. R. Evid. 201(b). *See United States v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431, 439 (E.D. Pa. 2020) ("[T]he Court may take judicial notice of public records such as those issued by CMS.").

Thus, to prove falsity under either program, Relators needed to show what the applicable states' coverage rules were for the alleged uses of Prezista and Intelence in this case, but they failed to do so either in briefing or at trial.[26]

No showing at all has been made as to the states' applicable laws. To the extent the states' coverage rules could be construed as a factual question, judgment as a matter of law should follow as a matter of course because Relators called no witnesses with knowledge of this question. Instead, their witnesses acknowledged that state coverage rules varied. (*E.g.*, 5/13/24 Tr. 1088:13-15 (Wilhelm agreeing that "each individual state has different requirements for what they allow to be paid under Medicaid"); 5/8/24 Tr. 472:11-473:1 (Strand admitting she does not know state-specific requirements but acknowledging that they vary from one state to the next).)

Relators' omission is no mere technicality. There is good ground to believe that most if not all of the states at issue ***covered*** off-label prescriptions for HIV medication during the time period at issue. Relators' own witness, Donna Graham, acknowledged that "New York . . . was one of the most generous states" when it came to reimbursement by Medicaid or ADAP for off-label HIV medications.

[26] For the same reason, as elaborated in Janssen's new-trial brief, it was erroneous to instruct the jury that it must find Janssen liable under the state FCAs if it found Janssen liable under the federal FCA. *See* New Trial Brief at 27-28.

(5/8/24 Tr. 470:3-8.) And by way of further example, a 1994 study reported that, in response to a survey, more than 30 states indicated that their Medicaid programs "allow[ed] [HIV] drugs to be used for unlabeled indications."[27] Only ***three*** of the 27 states that responded that they did not cover unlabeled indications—the District of Columbia, Rhode Island and Texas—are purportedly represented by Relators in this case.

In short, the details of the applicable state Medicaid and ADAP coverage regimes are critical to the question of liability in this case, but Relators provided no law, and no facts. Courts have repeatedly dismissed claims—as early as at the pleading stage—where, as here, the relator's theory is that the defendant caused submissions of false claims for prescription drugs to state Medicaid programs, but the relator fails to demonstrate that the state in fact would not cover the prescriptions at issue. *See, e.g., United States ex rel. Schieber v. Holy Redeemer Healthcare Sys., Inc.*, No. 19-12675, 2024 WL 1928357, at *8 (D.N.J. Apr. 30, 2024) (dismissing state-law FCA claims as a matter of law where the relator failed to establish that the alleged conduct involved the submission of information

[27] Robert J. Buchanan & Scott R. Smith, *Medicaid Policies for HIV-Related Prescription Drugs*, 15(3) Health Care Fin. Rev. 43 (1994) (attached as Ex. 18). Janssen relies on this article solely for illustrative purposes, not as substantive evidence of the applicable Medicaid or ADAP requirements, as to which Janssen has no burden of proof.

"relevant to . . . Medicaid [in] any of the other 26 states and the District of Columbia") (alterations in original) (citation omitted); *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 506 (E.D. Pa. 2016) (similar); *Carson v. Select Rehab., Inc.*, No. 15-5708, 2023 WL 5339605, at *21 (E.D. Pa. Aug. 18, 2023) (similar); *United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 295 (D. Mass. 2012) (state FCA claims failed as a matter of law where relators did not establish that off-label prescriptions would not be paid by state Medicaid programs at issue), *reversed on other grounds by United States ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134 (1st Cir. 2020). For identical reasons, Janssen is entitled to judgment notwithstanding the verdict on the state claims here.

B. Relators Failed To Prove Their State-Law Claims For Several Additional Reasons.

Even assuming that each state's Medicaid and ADAP programs adopted coverage requirements identical to Medicare, Relators' state-law claims also fail for the reasons set forth with respect to their federal claims above: they failed to proffer sufficient evidence to prove causation, materiality or falsity. (*See* § I, *supra*.) *Cf. United States ex rel. Travis v. Gilead Scis., Inc.*, 596 F. Supp. 3d 522, 543 n.159 (E.D. Pa. 2022) (State and federal claims "succeed or fall together" where "no party has alleged a material difference between the standards applicable to the FCA and equivalent state laws.").

For these reasons, too, Janssen is entitled to judgment as a matter of law on Relators' Medicaid and ADAP claims.

III. THE EVIDENCE DOES NOT SUPPORT THE VERDICT ON THE NUMBER OF CLAIMS OR DAMAGES.

Janssen is also entitled to judgment notwithstanding the verdict on the number of claims and the amount of damages for at least four reasons: (1) Relators' damages model was based on the wrong measure of damages; (2) Relators' damages model was based on assumptions they failed to prove at trial; (3) the number of claims and amount of damages found by the jury were arbitrary and have no basis in the evidence; and (4) at a minimum, in the event the Court holds that Relators' state-law claims fail as a matter of law, there is no way to determine the amount of federal damages or the number of federal false claims the jury found because of the nature of the verdict form.

A. Relators Failed To Prove That The Government Lost The Benefit Of Its Bargain.

In an FCA case, "the damages are essentially similar to those sustained when a defective article is purchased in a fraudulent transaction. In those instances, decisional law sets the damages as ***the difference in cost between that contracted for and that received***." *United States v. Hibbs*, 568 F.2d 347, 351 (3d Cir. 1977) (emphasis added). As courts have explained, "False Claims Act damages are meant to 'put[] the government in the same position as it would have been if the

defendant's claims had not been false.'" *United States ex rel. Davis v. District of Columbia*, 679 F.3d 832, 839 (D.C. Cir. 2012) (alteration in original) (citation omitted). "Thus, '[t]o establish damages, the government must show not only that the defendant's false claims caused the government to make payments that it would have otherwise withheld, but also that the performance the government received was worth less than what it believed it had purchased.'" *Id.* (alteration in original) (citation omitted).

Contrary to this precedent, Relators argued that the government is entitled to a full refund as a matter of course, and their proffered damages model is inalterably premised on this assumption. This argument fails as a matter of law.[28]

First, Relators' contention that they are entitled to seek a complete refund of what the government paid under the FCA is wrong. They ignore the general rule of lost value reflected in the Third Circuit's ruling in *Hibbs* and instead rely on inapposite cases in which "there [was] no tangible benefit to the government and the intangible benefit [was] impossible to calculate." *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 473 (5th Cir. 2009) (cited in Rels.' Trial Br. ("RTB") at 34 n.26, 35 n.27, Dkt. 351). This exception is limited to

[28] For the same reason, as elaborated in Janssen's new-trial brief, the instruction to the jury on damages was erroneous because it told the jury that the proper measure of damages was the "full amount paid" by the government. *See* New Trial Brief at 29-32.

situations where, for example, "the government had doled out grant monies directly to third-parties for specified, 'intangible' research projects, but the awardees had failed to effectuate that research." *United States ex rel. Concilio De Salud Integral De Loiza, Inc. v. J.C. Remodeling, Inc*., 962 F.3d 34, 43-44 (1st Cir. 2020) (citing *Longhi*, 575 F.3d at 473 and *United States ex rel. Feldman v. van Gorp*, 697 F.3d 78, 86-87 (2d Cir. 2012) (cited in RTB at 34 n.26)). In such cases, "the government was out of a fixed sum of money with ***nothing at all*** in return and therefore the courts found that recompense of the full contract price was all that could make the government whole." *Id.* at 44 (emphasis added).

In truth, these cases are simply a specific application of the general rule about lost value: the government paid for something but received nothing measurable, meaning that the difference between the price paid and the value received was the entire payment. But that is not the case here, where the government paid for Prezista and Intelence, which provided effective treatment for patients with HIV. Relators did not meet their burden of proving actual damages by showing that the government paid for something "valueless," such as "research that was never consummated." *Concilio De Salud*, 962 F.3d at 43-44 (citation omitted). Accordingly, their claim to recover the entire price of what was paid for Prezista and Intelence must be rejected.

Second, Relators' argument that the government received no value here because the medications it purchases are not sent to the government itself also lacks merit. The medications went to patients whose doctors determined they were medically necessary—precisely the third-party benefit for which the government paid. In similar circumstances, courts have upheld the application of the general rule that damages are equal to the difference in value (if any) rather than a complete refund. *See, e.g.*, *United States v. Killough*, 848 F.2d 1523, 1532 (11th Cir. 1988) (holding that the appropriate measure of damages was the difference between what the government paid and "the fair market value . . . of the goods or services provided" to the state of Alabama, even though the federal Government was not the recipient of the goods or services). The same rule applies here. Indeed, the uncontroverted record evidence showed that Prezista was priced at parity with its competitor drugs, demonstrating that the government paid fair market value for the goods provided. *See supra* at 21. Because Relators failed to proffer any evidence on the question of lost value, the jury's damages finding lacks a proper evidentiary basis.

B. Relators' Damages Model Is Not Substantial Evidence Because Its Assumptions Were Disproven By Relators' Own Witnesses.

Relators also failed to prove damages and alleged number of false claims because the evidence they proffered was unreliable and lacked factual basis. Specifically, as detailed in Janssen's motion to strike the testimony of Shaked and

Ian Dew (Dkt. 402), Relators' damages experts' calculations relied on several expansive factual assumptions that Relators did not prove at trial. And even when they relied on actual data, significant limitations rendered it unreliable. (*See* 5/31/24 Tr. 5294:18-5295:13 (Dew testifying that he could not identify in the pharmacy data which claims were private insurance versus government, and some of the data did not have any dates).) Because no jury could accept Shaked or Dew's calculations based on the factual record in this case, Relators had no admissible damages evidence, and for this reason too, Relators have failed to prove any damages or the number of false claims as a matter of law.

C. The Jury's Finding On The Number Of False Claims And The Amount Of Damages Was Arbitrary And Unsupported.

Regardless of the sufficiency of Shaked's damages model, it is clear that the jury rejected it and substituted its own, arbitrary assessment of the number of false claims (159,574) and amount of damages ($120,004,736 under the federal FCA and $30,001,184 under state FCAs). (*See* Verdict Form at 2, 4-5, Dkt. 435.) These findings lack evidentiary support.

Where a jury plainly rejects a damages expert's proposed damages amount, it may not simply "reduce the figures to reflect only compensable losses" in the absence of a "reduction formula prepared by an expert" to guide such an exercise. *See R.S.E., Inc. v. Pennsy Supply, Inc.*, 523 F. Supp. 954, 970 (M.D. Pa. 1981) (citing *Coleman Motor Co. v Chrysler Corp.*, 525 F.2d 1338 (3d Cir. 1975)). In

such circumstances, a jury cannot support an alternative damages amount "without resorting to guesswork or speculation." *Id.* at 971. Any damages amount found by a jury in this fashion must be set aside and judgment granted to the defendant notwithstanding the verdict. *See id.* at 971-72.

That is the case here, and the logic of *R.S.E.* applies both to the jury's finding on damages and its finding of the number of false claims. Shaked suggested total damages amounts of either $446.7 million or $361.9 million for off-label claims, reflecting either 593,996 or 481,265 allegedly false claims, respectively. (*See* 6/3/24 Tr. 5484:23-5485:15, 5493:14-25.) He also enumerated damages estimates specific to each of Relators' theories of improper promotion: $414.3 million for lipids; $1.9 million for Prezista treatment-naïve; $32.4 million for Intelence once-daily; and $16.4 million for Intelence treatment-naïve. (*Id.* 5487:18-5489:13.)

But the jury did not select any one (or any combination) of these amounts. Instead, it selected entirely different numbers: $150,005,920 in total damages, and 159,574 claims. (*See* Verdict Form at 2, 4-5, Dkt. 435.) There is no discernible connection between the jury's findings and any estimate provided by Shaked. Nor did Shaked furnish the jury with any "reduction formula" by which it could have derived these findings from the estimates Shaked provided. As a result, the jury's

findings on the amount of damages and the number of claims rests on "guesswork or speculation" and cannot be sustained. *R.S.E.*, 523 F. Supp. at 970-72.

D. At A Minimum, The Jury's Findings On Federal Damages And The Number Of Claims Cannot Be Sustained.

Alternatively, and at a minimum, the Court should vacate the jury's finding as to the amount of federal damages and the number of false claims. As the Court forecast right before closing, Relators' insistence on a verdict form that did not allow the jury "to allocate damages to each state, . . . to make a determination as to the number of false claims per state," or even "to determine the number of false claims for the states as a group" has caused "a greater issue." (6/11/24 Tr. 7906:13-25.) Because Relators' state-law claims fail as a matter of law for the reasons set forth in § II, *supra*, the jury's finding of the number of claims cannot be sustained because it includes federal and state claims, with no basis in the record to disaggregate them. That failure poses an insurmountable problem for the Court's calculation of the required civil penalties. *See* 31 U.S.C. § 3729. And its "federal" damages finding also cannot be sustained because it comprises payments not only by Medicare but also by ADAP and (to the extent of the federal portion) Medicaid, which similarly cannot be separated out based on any evidence in the record.

"The general rule is that one of two or more issues submitted to the jury was submitted erroneously, a general verdict cannot stand." *Morrison Knudsen Corp. v. Firemen's Fund Ins. Co.*, 175 F.3d 1221, 1256 n.45 (10th Cir. 1999). That is what

happened here. At Relators' insistence, no separate amount for ADAP damages was provided on the verdict form. Over Janssen's objection, no separate blank was provided to the jury to distinguish between alleged false claims presented to Medicare from those allegedly presented to state payors. (*See* Verdict Form at 2, 4-5; *see also* 6/11/24 Tr. 7901:3-21, 7904:13-17, 7949:5-12.) Instead, Relators' counsel insisted on combining damages amounts for Medicare, ADAP and the federal portion of Medicaid because it "all goes back to the United States," and that one blank for claims would suffice to encompass "ADAP, Medicaid, Medicare." (*Id.* 7904:6-8, 7949:13-16.)

As a result, in light of its return of verdict for Relators on both federal and state claims, the jury's finding of $120,004,736 in federal damages constitutes an unknown combination of dollars paid by Medicare, Medicaid and ADAP, and its finding of 159,574 claims constitutes an unknown combination of claims made to those payors. There is now no way to "reverse engineer" the jury's finding and separate the federal and state damages or claims to isolate the federal damages or number of claims. (*Id.* 7951:1-6.) Indeed, the jury specifically asked for help on this issue during deliberations because it was "unable to locate [Shaked's] testimony or any exhibit associated that testimony[]" "detailing the number of federal versus individual state claims." (*Id.* 8311:8-13.) For this reason, in the event the Court determines that Janssen is entitled to judgment as a matter of law

as to Relators' state-law claims—or even if the Court agrees with Janssen that Relators failed to prove just one of its state-law claims—it should also reject the jury's finding as to the federal damages and number of claims because there is no evidentiary basis for these quantities and no evidence in the record that would support any other numbers in their place.

IV. RELATORS' CLAIMS ALSO FAIL BECAUSE THEY ARE BARRED FOR MULTIPLE REASONS.

A. The FCA's Government-Action And Public-Disclosure Bars Foreclose Relators' Claims.

Janssen is also entitled to judgment as a matter of law on Relators' claims because the evidence at trial established that the FCA's government-action and public-disclosure bars apply in light of the 2010 CIA.

First, the government-action bar forecloses qui tam suits that are "based upon allegations or transactions which are the subject of . . . an ***administrative civil money penalty proceeding*** in which the Government is already a party." 31 U.S.C. § 3730(e)(3) (emphasis added). The government-action bar precludes Relators' claims because of the prior FCA action and resulting 2010 CIA. *See United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011, 1021 (9th Cir. 2017) (prior settled intervened FCA suit for similar allegedly conduct triggers bar). Like this case, the one giving rise to the 2010 CIA focused on off-label marketing—a parallel Relators stressed repeatedly at trial. And there is no question that CIA's provisions

included Prezista and Intelence in its scope and afford the government the option to seek stipulated penalties in the event it believed Janssen was engaged in off-label marketing of these drugs. (*See* RX-423, §§ II.A, II.C.3-5, VII, X.A, X.A.1.)

In short, the prior FCA suit and resulting 2010 CIA created an ongoing proceeding in which the HHS-OIG was looking for and could have penalized Janssen for the conduct that is the focus of Relators' allegations here. For that reason, the government-action bar applies and bars all of Relators' claims.

Second, the public-disclosure bar also forecloses Relators' claims. This bar applies when substantially the same allegations or transactions of the claimed fraud were publicly disclosed through statutorily identified sources, at least where the relator is not an original source of the information and does not materially add to publicly disclosed information. *See United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299, 304-05 (3d Cir. 2016) (citation omitted).

The bar was held to apply in similar circumstances by the Sixth Circuit in *Maur*, 981 F.3d 516. There, as here, the defendant was subject to a CIA arising from a prior FCA action, which "undoubtedly qualifies as a" relevant public disclosure. *Id.* at 522. The Relators in that case sought to circumvent the bar in part by arguing that their evidence was not "substantially the same" as the previously disclosed alleged fraud but the Court rejected this argument, explaining that new

evidence of fraud is substantially the same as long as the prior disclosure "put the government on notice of the fraud alleged." *Id.* at 526 (cleaned up). This is so even when the relator "adds new details to describe essentially the same scheme," or when the new details suggest a broader dimension to the previously alleged fraud. *Id.* (cleaned up). For similar reasons, the Court also rejected the relator's argument that he was an original source by virtue of adding materially to previously disclosed information, explaining that by virtue of the governments ongoing oversight under the CIA, "it can be assumed that the government would be aware if the fraudulent scheme continued or was restarted." *Id.* at 528 (cleaned up).

The same is true here. The 2010 CIA imposed oversight specifically as to off-label marketing, as to all Janssen drugs. (*See* RX-423, § II.C.3-5; *see also* 5/28/24 Tr. 3868:37 ("Q. And so the very products and the very programs, like speaker programs, that are at issue here in this lawsuit were part of that corporate integrity agreement. Correct, ma'am? A. That is right.").) Its purpose was to prevent off-label or kickback schemes of the sort alleged by Relators, prompted by the government's conclusion that such conduct had occurred in connection with some of Janssen's other products. As in *Maur*, Relators merely attempt to "provid[e] additional instances of the same type of fraud during the oversight period." 981 F.3d at 528. Accordingly, their claims are also foreclosed under the government-disclosure bar.

B. Relators' Claims Are Constitutionally Barred.

Finally, Relators' claims are also barred as a constitutional matter. Multiple Supreme Court Justices have noted that "[t]here are substantial arguments that the [False Claim Act's] *qui tam* device is inconsistent with Article II." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 442 (2023) (Kavanaugh, J., concurring) (first alteration in original). That is because FCA relators exercise executive power in pursuing claims on behalf of the government. *See id.* at 449-50 (Thomas, J., dissenting).

"To the extent that delegation of executive power to a *private* entity outside the government is permissible at all, it is permissible only if that entity 'is adequately subject to Presidential control.'" *Consumers' Rsch., Cause Based Com., Inc. v. Fed. Commc'ns Comm'n*, 88 F.4th 917, 937 (11th Cir. 2023) (emphasis added) (citing *Dep't of Transp. v. Ass'n of Am. Railroads*, 575 U.S. 43, 91 (2015)), *cert. denied*. Applying this concept, the Supreme Court has developed a "sufficient control" test, under which relevant considerations include the ability of the President to remove the entity exercising executive power; the limitations on the appointment of such entities; whether they must abide by Department of Justice policy, and whether the entity may exert its powers against only public defendants or also private, the latter giving rise to greater concern. *See Morrison v. Olson*, 487 U.S. 654, 696 (1988).

The FCA does not impose sufficient control on the exercise of executive power by private relators in a non-intervened case. The government imposes no limitation on the scope of a relator's lawsuit; the relator is not required to adhere to Department of Justice policy[29]; a relator exercises the government's power against private actors; and a relator may not be "removed" in the traditional sense. The FCA thus fails to require or even permit "sufficient control" over private relators in declined cases. As a result, the FCA is unconstitutional as applied in this case, and the Court should grant judgment as a matter of law on this ground as well.

CONCLUSION

In light of Relators' fundamental failure of proof on several elements of their claims, and for the other reasons detailed above, the Court should grant Janssen judgment as a matter of law.

[29] Indeed, the Department itself has recognized that *qui tam* relators can act, and have acted, contrary to the public interest when wielding executive power in instituting actions on the government's behalf. Memorandum from Michael Granston, Dir., Commercial Lit. Branch, Fraud Div., *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)* (Jan. 10, 2018) (attached as Ex. 19); *see also* Memorandum Op. for the Att'y Gen. from William P. Barr, Assistant Att'y Gen., Off. of Legal Couns., *Constitutionality of the Qui Tam Provisions of the False Claims Act* 207-08, 217-18 (Jul. 18, 1989) (observing that a "relator is empowered to prosecute the government's claim even when the Attorney General has determined that there is no valid claim or that pursuing the suit is not in the interests of the United States") (attached as Ex. 20).

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